

Pimpare, Justin

From: Pimpare, Justin
Sent: Monday, July 29, 2019 5:00 PM
To: Pierre-Louis, Alix
Subject: RE: Category Determination Request Letter - EMD Millipore

Ok thanks. I will cc you on the response I send this week
Jay

From: Pierre-Louis, Alix <Alix.Pierre-Louis@mwra.com>
Sent: Monday, July 29, 2019 3:31 PM
To: Pimpare, Justin <Pimpare.Justin@epa.gov>
Subject: FW: Category Determination Request Letter - EMD Millipore

Hi Jay,

I just called and left you a voice mail message. Peter is on vacation and had asked me to call and inform you that we are ok with the fact that EMD Millipore is not covered under the categorical standard based on Bob Capaccio's response to your request. Please feel free to call me if you have any questions. Thanks

Alix Pierre-Louis
Regional Manager
Toxic Reduction and Control
MWRA
Phone: 717 305-5660

From: Pimpare, Justin <Pimpare.Justin@epa.gov>
Date: July 29, 2019 at 12:27:07 PM EDT
To: Yarossi, Peter <Peter.Yarossi@mwra.com>
Subject: [EXTERNAL] FW: Category Determination Request Letter - EMD Millipore

[EXTERNAL]: This is an external email. Do not click on links or attachments if sender is unknown or if the email is unexpected.

Any thoughts on this... I have to say given the language below.. I would be inclined to say they fall out of cat standards... as you know, MWRA can permit them however you choose.

Let me know if you have any questions

Jay

From: Pimpare, Justin
Sent: Thursday, July 18, 2019 8:34 PM
To: Yarossi, Peter <Peter.Yarossi@mwra.com>
Subject: FW: Category Determination Request Letter - EMD Millipore

I spoke with Bob on the phone today after our email exchange and wanted to follow up with you as well. Here is his response to my request for more information. Will try and give you a call in the AM.

Jay

From: Bob Capaccio <rscapaccio@verizon.net>
Sent: Thursday, July 18, 2019 3:29 PM
To: Pimpare, Justin <Pimpare.Justin@epa.gov>
Cc: Bobby.Young@emdmillipore.com
Subject: Re: Category Determination Request Letter - EMD Millipore

Good afternoon Jay,

Based on our earlier discussion, I am submitting additional clarification on behalf of my client EMD Millipore relative to their category determination request.

A small percentage (<10%) of the molecules that the EMD Millipore Burlington facility synthesizes, purchases, QCs, packages and ships to their warehouses have ingredients identical to a "pharmaceutical" with respect to chemical structure. However, none of the molecules are classified as pharmaceuticals and cannot be administered to humans or animals. All the products that are handled are positioned for strictly non-human use and are used by the life science research community as basic research tool compounds to aid in the understanding of the biological mechanisms.

By way of an example, EMD Millipore currently sells sumatriptan, a chemical compound which their customers purchase to use in their basic research to help them better understand the biological targets and mechanisms through which sumatriptan mediates its effects in the hope of developing better antimigraine drugs. However, none of our customers will be either administering MilliporeSigma sumatriptan to themselves for the treatment of migraine nor incorporating it into final pharmaceutical products.

I hope the above explanations help. Please let me know if I can be of any further assistance.

Best Regards, Bob

Robert S. Capaccio, PE
Consulting Engineer
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Sudbury, MA 01776

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-----Original Message-----

From: Pimpare, Justin <Pimpare.Justin@epa.gov>
To: Bob Capaccio <rscapaccio@verizon.net>
CC: Bobby.Young@emdmillipore.com <Bobby.Young@emdmillipore.com>
Sent: Thu, 18 Jul 2019 13:20
Subject: RE: Category Determination Request Letter - EMD Millipore

Hi Bob,

I have reviewed the request letter and have also spoken with MWRA regarding the operations conducted at the facility. However, in order to provide a determination, I feel more information is needed. Specifically, what are the processes

conducted at the facility and what is the final product? It would be helpful to have a more detailed explanation of the process and final product so that I can provide you with a determination. The response can be done by email. Thank you and please feel free to call me with any questions.
Jay

Justin Pimpare
Regional Pretreatment Coordinator
5 Post Office Square
Suite 100 OEP 06-03
Boston, MA 02109
617 918 1531

From: Bob Capaccio <rscapaccio@verizon.net>
Sent: Friday, June 28, 2019 4:50 PM
To: Pimpare, Justin <Pimpare.Justin@epa.gov>
Cc: Bobby.Young@emdmillipore.com
Subject: Category Determination Request Letter - EMD Millipore

Good afternoon Jay,

I have attached a copy of our letter requesting a decision by the EPA relative to the appropriate classification of EMD Millipore's Burlington, MA facility. A "hard copy" is on its way to you via Fed Ex. Please call me should you have any questions or need further information. Thank you and have a great 4th of July.

Best Regards, Bob

Robert S. Capaccio, PE
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